



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

3 2 3 9 5 AUG 18 P 2 :20

JUL 29 2005

Ms. Candis L. Scott
CEO
Highland Laboratories
110 South Garfield
P.O. Box 199
Mt. Angel, Oregon 97362

Dear Ms. Scott:

This is in response to your letter of July 5, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that Highland Laboratories intends to make the following statements, among others, for the Product Corti Response™ : "[R]educe STRESS; Elevate Mood." These claims are made in the context that the product is intended to reduce excess cortisol levels that are described as being associated with, among other things, diseases such as abdominal obesity, high blood sugar, bone loss immune problems, hippocampus atrophy, fluid retention and hypertension, depression, social withdrawal, insomnia and anxiety.

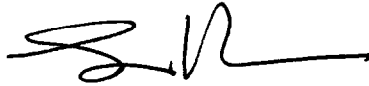
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, namely, those associated with excess cortisol secretion. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975 0163 LET 837

Page 2 - Ms. Candis L. Scott

Please contact us if we may be of further assistance.

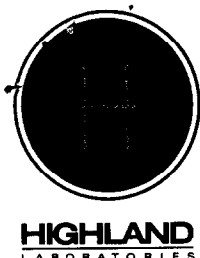
Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340



110 South Garfield
P.O. Box 199
Mt. Angel, OR 97362
(800) 547-0273
(503) 845-9223
Fax (503) 845-6364

www.highlandvitamins.com
www.highlandcustom.com

July 5, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FDA
200 C Street, SW
Washington, DC 20204

JUL 13

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, **Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362**, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

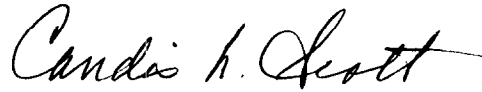
Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Corti Response™	Chromium 120 mcg. Holy Basil 375 mg. Cocoa Seed 325 mg. Magnolia Brk 300 mg. Green Tea 250 mg. Ashwaganda 125 mg. Passion Flower 125 mg. L-Theanine 100 mg. Banaba Ext 10 mg. Vanadyl Sulfate 6 mg.	Reduces stress and elevates mood. Supports normal range blood sugar level. <i>Please see attachment 1</i>

#1286

2005-4361
AIMS

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, reading "Candis L. Scott". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

Candis L. Scott
CEO Highland Laboratories

Attachment 1
Highland Laboratories

Corti Response™

The “fight or flight” response in humans is built into the oldest part of our brains. It is this survival capability that has allowed the human race to thrive against such fierce natural odds.

When faced with outside threats, the brain sends a warning to the hypothalamus, the pituitary and adrenal glands which respond by secreting hormones. The end product is cortisol, which is delivered to the vascular system by the adrenal glands. Cortisol is necessary for normal brain, immune, muscle and blood sugar function and blood circulation.¹

The net effect of constant stress is excess cortisol in the blood stream which, among other things, causes abdominal obesity, high blood sugar, bone loss, immune problems, hippocampus atrophy, fluid retention and hypertension.^{2,3} Other expressions of too much cortisol includes fatigue, irritability, depression, social withdrawal, insomnia and anxiety.⁴

Corti Response™ is formulated to support and balance normal function.

Reduce STRESS; Elevate MOOD

Holy Basil Herb (*Ocimum sanctum*) is considered sacred by many consumers – on many continents - because of its affect on mood and mental acuity. Attaining health begins with optimism and basil is to humans as wings are for birds.

Cocoa Seed Extract (*Theobroma cacao*) is the main ingredient in chocolate, and everybody knows how this delicacy brings solace to an aching heart or pleasure to a nerve-wracking day. Greet each day with a smile and a contented sigh, knowing you’re supported naturally, without fat or sugar.

Magnolia Bark (*Magnolia officinalis*) The Chinese have used this for 2000 years as a way to calm and wick away stress. We use a 4:1 extract in our formula.

Green Tea Leaf extract (*Camilla sinensis*) continues to gain popularity in the US diet is marketed in Japan as a supplement for supporting normal mental health. The active polyphenols are a stronger antioxidant than vitamin C. It is also a major natural source for L-theanine, a non-protein amino acid.

Ashwaganda (*Withania sominfera* root) is also referred to as Indian ginseng, used in Ayurvedic medicine for reducing stress. Why argue with anecdotal evidence with more than two millennia of experience?

Passion Flower Herb (*Passiflora incarnate*) also has a calming effect and was used widely by the Aztecs as a mild sedative. Notice the botanical reference to a higher power? That’s what you can expect with this product – tapping into a higher power, including your own!

Healthy Glucose Levels for those who are within normal levels

Chromium – Corti Response has 120 mcg., which helps to support normal glucose levels. Chromium works closely with insulin in the uptake of glucose into cells.

Vanadyl Sulfate - the most popular supplemental form of Vanadium. This formula has 6 mg. of this very important mineral. Vanadyl sulfate also helps normal metabolizing of glucose.

Banaba Standardized Extract (*Lagerstroemia speciosa* leaf) – is another traditional plant used in Southeast Asia and is thought to be a correspondent in a normal uptake process – where cells turn glucose into energy.

References:

1. Guyton, A. and Hall, J., Textbook of Medical Physiology. Philadelphia: W.B. Sanders; 2000: 869-83
 2. Carpenter, W. et al. "Cortisol's effects on human mental functioning." J Clin Psychopharmacol 1982, 2: 91 – 101
- Sapse, A. Med Hypoth 1984